Proposed Maximum Residue Limit PMRL2008-05

Fludioxonil

(publié aussi en français)

22 April 2008

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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ISBN: 978-0-662-48487-5 (978-0-662-48488-2)
Catalogue number: H113-24/2008-5E (H113-24/2008-5E-PDF)

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Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* (PCPA), is proposing to establish maximum residue limits (MRLs) for fludioxonil on imported beans (Crop Group 6 bean commodities) and leafy greens (Crop Subgroup 4A, except spinach) to permit the import and sale of food containing these residues. See Appendix I for a list of crop group commodities.

Fludioxonil is a fungicide used to control specific disease organisms on the imported commodities. It is currently registered in Canada as a seed treatment for use on a number of fruit, vegetable, legume, cereal, oilseed and herb/spice commodities and more recently as a foliar application (Switch 62.5 WG Fungicide) and postharvest dip (Scholar 50WP Fungicide) on certain fruits and vegetables.

The PMRA has determined the quantity of residues that are likely to remain in or on the imported commodities when fludioxonil is used according to label directions in the exporting country. The Agency has also determined that such residues will not pose an unacceptable dietary health risk, and is proposing to legally establish corresponding import MRLs. An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

Details regarding the establishment of these import MRLs can be found in the corresponding Evaluation Report that is available on the PMRA website, under Public Registry, Product Information, Current Applications.[1]

Currently, MRLs are legally established under the Food and Drug Regulations (FDR) after consultation through the *Canada Gazette*. Amendments to the *Food and Drugs Act* (FDA) via Bill C-28, anticipated to come into force in 2008, will allow pesticide MRLs to be legally established under the PCPA without having to adopt MRLs by regulation under the FDA. This will result in a more efficient means of establishing, revising and revoking pesticide MRLs.

Consultation on the proposed import MRLs for fludioxonil is being conducted via this document (see Next Steps). This action is being taken in advance of Bill C-28 coming into force to allow the MRLs to be legally established as soon as possible after the FDA is amended.

MRLs have been legally established in Canada for fludioxonil on a number of food commodities and over 300 additional MRLs have been proposed in PMRL2006-01, PMRL2007-10 and PMRL2007-13. MRLs of 0.01 ppm were proposed for the bean and leafy vegetable commodities covered by this PMRL in PMRL2006-01, based upon fludioxonil use as a seed treatment, but are being amended as a result of this action to accommodate the use pattern in the exporting country.

The proposed import MRLs for fludioxonil in Canada in or on food, to be added to those MRLs already legally established, are as follows.

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[1] The relevant report can be accessed by selecting the Applications/Amendment/Historical tabs and opening the Evaluation Report found under Application Number 2005-2328.

Table 1 Proposed Maximum Residue Limits for Fludioxonil

Common Chemical Name	Chemical Name of Substance	Food Commodities	MRL Proposed in PMRL2006-01 (ppm)	Proposed MRL (ppm)
Fludioxonil	4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1*H*-pyrrole-3-carbonitrile	Leafy greens* (Crop Subgroup 4A, except spinach)	0.01	30
		Beans*	0.01	0.4

* See Appendix I for a list of corresponding commodities.

A complete list of all MRLs established in Canada can be found in Table II, Division 15 of the FDR. Once the amendments to the FDA via Bill C-28 are in force, the list of legally established Canadian MRLs will be available on the PMRA's MRL webpage, which will be updated to include the MRLs listed in this document.

International Situation and Trade Implications

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the locations of the field crop trials used to generate residue chemistry data. The proposed Canadian MRLs are the same as corresponding tolerances for beans and leafy greens established in the United States (listed in 40 CFR Part 180 by pesticide). Table 2 identifies differences between Canadian MRLs, American tolerances and Codex[2] MRLs (Codex MRLs searchable by pesticide or commodity).

[2] Codex is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Table 2 Comparison of Canadian MRLs, American Tolerances and Codex MRLs

Food Commodities	Canadian MRLs (ppm)	American Tolerances (ppm)	Codex MRLs (ppm)
Leafy greens subgroup except spinach	30	30	10 (Lettuce, head only)
Beans, dry and succulent	0.4	0.4	0.07 (Beans, dry) 0.03 (Beans, shelled) 0.3 (Beans, except broad bean and soya bean)

Next Steps

The PMRA invites the public to submit written comments on the proposed MRLs for fludioxonil up to 75 days from the date of publication of this document. Please forward your comments to Publications (see contact information on the cover page of this document). The PMRA will consider all comments received prior to making a final decision on the proposed MRLs for fludioxonil and posting an Established Maximum Residue Limit (EMRL) document on the PMRA's website once the amendments to the FDA are in force.

Appendix I

Crop Groups: Numbers and Definitions

Crop Group Number	Name of the Crop Group	Food Commodities Included in the Crop Group
4A	Leafy vegetables, except Brassica Leafy greens subgroup, except spinach	Amaranth Arugula Corn salad Dandelion leaves Dock Edible leaved chrysanthemum Endives Fresh chervil leaves Garden cress Garden purslane Garland chrysanthemum Head lettuce Leaf lettuce Orach leaves Parsley leaves Radicchio Upland cress Winter purslane
6	Legume vegetables (bean commodities only)	Dry adzuki beans Dry beans Dry blackeyed peas Dry broad beans Dry catjang seed Dry chickpeas Dry guar seed Dry kidney beans Dry lablab beans Dry lentils Dry lima beans Dry moth beans Dry mung beans Dry navy beans Dry pink beans Dry pinto beans Dry rice beans Dry tepary beans Dry urd beans Edible-podded jackbeans

Crop Group Number	Name of the Crop Group	Food Commodities Included in the Crop Group
		Edible-podded moth beans Edible-podded runner beans Edible-podded snap beans Edible-podded swordbeans Edible-podded wax beans Edible-podded yardlong beans Grain lupin Mung bean sprouts Succulent shelled blackeyed peas Succulent shelled broad beans Succulent shelled lima beans